Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

Claims 1-40 (Cancelled)

41. (Previously presented) A method for determining a predisposition for developing prostate cancer or a presence of prostate cancer in a patient comprising:

(a) obtaining a urine sample from a patient, said sample comprising at least one prostate cell or nucleic acid extract thereof, and not comprising semen;

(b) performing an RNA amplification assay on said urine sample, using a first primer pair specific to a prostate cancer-specific PCA3 mRNA sequence selected from the group consisting of:

i) a polynucleotide comprising SEQ ID NO: 9, 10 or 13;

ii) a polynucleotide sequence that hybridizes under high stringency conditions to the polynucleotide sequence in i), wherein said high stringency conditions comprise a hybridization at 65°C in 6X SSC or 5X SSPE, 5X Denhardt's solution, 0.5% SDS and 100 μg/ml denatured carrier DNA and a washing at 65°C in 0.2X SSC/0.1% SDS; and

iii) a polynucleotide sequence fully complementary to i) or ii);

(c) performing a second RNA amplification assay on said urine sample, using a second primer pair specific to a prostate-specific mRNA sequence; and

(d) detecting said PCA3 mRNA sequence and said prostate-specific mRNA sequence;

whereby a detection of an elevated level of said prostate cancer-specific PCA3 mRNA sequence, as compared to a level thereof associated with a normal or non-malignant prostate state, is indicative of a higher risk of developing prostate cancer or a presence of prostate cancer in said patient; and

whereby an absence of detection of said prostate cancer-specific PCA3 mRNA sequence or lower level thereof, as compared to a level thereof associated with a

normal or non-malignant prostate state, is indicative of an absence of prostate cancer or a lower risk of developing same, when said prostate-specific mRNA is detected.

42. (Previously presented) The method of claim 41, wherein said RNA amplification assay is carried out in real-time.

43. (Previously presented) The method of claim 41, wherein said detection is performed by fluorescence, chemiluminescence or colorimetry detection.

44. (Previously presented) The method of claim 41, wherein the detection of said prostate-specific mRNA validates the presence of at least one prostate cell in said urine sample.

45. (Previously presented) The method of claim 41, wherein said prostate-specific mRNA is selected from the group consisting of: PSA, human kallikrein 2, PSMA, transglutaminase 4, acid phosphatase, PCGEM1 mRNA and a prostate-specific PCA3 mRNA that is not associated with prostate cancer.

46. (Previously presented) The method of claim 45, wherein said prostate-specific mRNA is PSA mRNA.

47. (Previously presented) The method of claim 46, wherein said PSA mRNA hybridizes to human kallikrein 2.

48. (Previously presented) The method of claim 41, wherein said RNA amplification method is selected from the group consisting of:

(a) nucleic acid sequence-based amplification (NASBA);

(b) polymerase chain reaction (PCR);

(c) transcription-mediated amplification assay (TMA); and

(d) ligase chain reaction.

49. (Previously presented) The method of claim 42, wherein said RNA amplification method is selected from the group consisting of:

(a) nucleic acid sequence-based amplification (NASBA);

(b) polymerase chain reaction (PCR);

(c) transcription-mediated amplification assay (TMA); and

(d) ligase chain reaction.

50. (Previously presented) The method of claim 41, wherein said amplification of PCA3 and said prostate-specific mRNA is performed simultaneously.

51. (Previously presented) The method of claim 41, wherein said amplification of PCA3 is carried out using a primer pair comprised of the polynucleotide sequences set forth in SEQ ID NOs: 3 and 4.

52. (Previously presented) The method of claim 41, wherein said detection of PCA3 is carried out using a molecular beacon that hybridizes to PCA3 under high stringency conditions.

53. (Previously presented) The method of claim 52, wherein said molecular beacon comprises the sequence set forth in SEQ ID NO: 6.

54. (Previously presented) The method of claim 46, wherein said amplification of PSA is carried out using a primer pair comprised of the polynucleotide sequences set forth in SEQ ID NOs: 1 and 2.

55. (Previously presented) The method of claim 46, wherein said detection of PSA is carried out using a PSA molecular beacon that hybridizes to PSA under high stringency conditions.

56. (Previously presented) The method of claim 55, wherein said PSA molecular beacon comprises the sequence set forth in SEQ ID NO: 5.

57. (Previously presented) The method of claim 50, wherein said simultaneous amplification is carried out in one container.

58. (Previously presented) The method of claim 46, wherein said detection of PSA is carried out using a chemiluminescent label in a homogenous detection method.

59. (Previously presented) The method of claim 43, wherein said detection of PCA3 is carried out using acridinium ester compounds.

60. (Previously presented) The method of claim 58, wherein said chemiluminescent label is an acridinium ester.

61. (Previously presented) The method of claim 41, wherein said mRNA is extracted from said at least one prostate cell.

62. (Previously presented) The method of claim 61, wherein said RNA is extracted using

(a) a silica based purification method; or

(b) a target capture method.

63. (Previously presented) The method of claim 41, wherein said urine sample is a voided urine sample.

64. (Previously presented) The method of claim 62, wherein said RNA is extracted using a silica-based method.

65. (Currently amended) The method of claim 63, wherein said voided urine sample is collected as the first voided urine following a digital rectal exam.

66. (Cancelled)

67. (Previously presented) A method for determining a predisposition for developing prostate cancer or a presence of prostate cancer in a patient comprising:

(a) obtaining a urine sample from a patient, said sample comprising at least one prostate cell or nucleic acid extract thereof, and not comprising semen;

(b) performing an RNA amplification assay on said urine sample, using a first primer pair specific to a prostate cancer-specific PCA3 mRNA sequence selected from the group consisting of:

i) a polynucleotide comprising SEQ ID NO: 9, 10 or 13;

ii) a polynucleotide sequence that hybridizes under high stringency conditions to the polynucleotide sequence in i), wherein said high stringency conditions comprise a hybridization at 65°C in 6X SSC or 5X SSPE, 5X Denhardt's solution, 0.5% SDS and 100 μg/ml denatured carrier DNA and a washing at 65°C in 0.2X SSC/0.1% SDS; and

iii) a polynucleotide sequence fully complementary to i) or ii);

(c) performing a second RNA amplification assay on said urine sample, using a second primer pair specific to a prostate-specific mRNA sequence; and

(d) detecting said PCA3 mRNA sequence and said prostate-specific mRNA sequence;

whereby a higher detection of said prostate cancer-specific PCA3 mRNA, as compared to a predetermined cut off value associated with a normal or non-malignant prostate state, is indicative of a higher risk of developing prostate cancer or a presence of prostate cancer in said patient; and whereby an absence of detection or lower detection of said prostate cancer-specific PCA3 mRNA, as compared to said predetermined cut off value associated with a normal or non-malignant prostate state, is indicative of an absence of prostate cancer or a lower

risk of developing same, when said prostate-specific mRNA is detected.

68. (Previously presented) The method of claim 41, wherein said detection of PCA3 is carried out using chemiluminescent labels in a homogenous detection method.

69. (Previously presented) The method of claim 68, wherein said detection of PCA3 is carried out using acridinium ester compounds.